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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,453

02/18/2005

Karsten Reihs

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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

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1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,453	<b>Applicant(s)</b> REIHS, KARSTEN	
	<b>Examiner</b> DENNIS M. WHITE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/30/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. "Alpha-cyano-4-hydroxycoumarin acid" is not supported in the specification and claims as a suitable MALDI matrix substance in such a way to enable one of ordinary skill in the art to make and use the invention. Alpha-cyano-4-hydroxycoumarin acid is not known in the art as a compound for MALDI mass spectrometry. The German priority document (DE 10258674.8) in claim 10 uses "alpha-cyano-4-hydroxyzimtsäure" which is translated to alpha-cyano-4-hydroxycinnamic acid. For further prosecution, the office is treating the compound as alpha-cyano-4-hydroxycinnamic acid.

4. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "by precipitation", and the claim also recites "preferably by sublimation" which is the narrower statement of the range/limitation.

6. Regarding claims 4, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Regarding claims 19, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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8. Claims 2-3, 5-18, and 20 are rejected as being dependent on claims 1 and 19.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Beecher et al (WO 00/67293).

Regarding claim 19, Beecher teaches a laser desorption time of flight mass spectrometer used with a probe comprising a film of self-assembled monolayer for example decane thiol on gold (“consisting of material impervious to water vapour and, preferably, impervious to light”) and MALDI matrix in the openings (“Long-time stable surface formation with at least one MALDI matrix point”) wherein the probe is in a vacuum chamber (“surrounded by a hollow body containing a vacuum”) (Pg. 10 lines 10-17).

Regarding claim 20, Beecher teaches the openings or feature comprises binding functionalities such as antibodies (“additional biological material on the MALDI matrix point”) (Pg. 5 lines 7-15 and Pg. 12 claim 7).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecher et al (WO 00/67293) in view of Dreyfus (USP 5,854,486).

Regarding claim 1, Beecher et al teach a method of producing a MALDI sample carrier with a surface formation with a multitude of MALDI matrix points, characterised in that the MALDI matrix points are deposited ("applied to the sample carrier") from the liquid phase (Pg. 11 lines 4-15). Beecher et al is silent about the MALDI matrix is applied by precipitation of a MALDI matrix substance from the gas phase, preferably by sublimation.

Dreyfus teaches a MALDI sample carrier in which the matrix material is deposited from the gas phase on to a substrate by sublimation. It is desirable to deposit the matrix material by sublimation from the gas phase because it provides pinhole free layers and the ability to vary the seed crystal density (col. 4 lines 26-51).

Therefore it would have been obvious to one of ordinary skill in the art to perform the depositing step of Bleech by using the known step of depositing by sublimation of the gas-phase MALDI matrix because it provides pinhole free layers and the ability to vary the seed crystal density.

Regarding claim 2, Beecher/Dreyfus teach that a film ("plate") (Figure 1:102) covers the substrate ("sample carrier") (Figure 1:101) during the precipitation from the gas phase, which has openings ("plate has through holes whose cross-sectional area corresponds to the cross-sectional area of the respective MALDI matrix points") where the matrix is deposited (Pg. 11 lines 4-15).

Regarding claims 3-5, Beecher/Dreyfus teach that the film has a plurality of openings that are arranged in an orderly fashion for easy addressability ("plate has at least one further through hole by means of which information is transferred to the sample carrier by precipitation of the MALDI matrix substance from the gas phase" "alignment points" "MALDI matrix points are arranged along a grid") (Pg. 8 lines 7-8).

Regarding claim 6, Beecher/Dreyfus teach the openings can comprise both affinity surface to capture the analyte and adding the energy absorbing material ("MALDI matrix points have substructures") (Pg. 2 lines 6-8).

Regarding claim 7, Beecher/Dreyfus teach the openings containing the MALDI matrix points are separated into several partial points, preferably isolated from one another (Figure 1: 103).

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Regarding claim 10, Beecher/Dreyfus teach the matrix comprises cinnamic acid derivatives such as .alpha.-cyano-4-hydroxycoumarin acid (Pg. 5 lines 31-34 and Hutchens et al USP 5,719,060 col. 6 lines 30-35).

Regarding claim 11-12, Beecher/Dreyfus teach the film comprises polymers such as polytrifluoroethylene and the matrix is cinnamic acid (“characterised in that the sample carrier has an ultraphobic surface” “characterised in that the MALDI matrix points or partial points represent hydrophilic areas which are completely surrounded by ultraphobic areas”) (Beecher: Pg. 5 line 31, Pg. 8 lines 19-28 and Figure 1:103, 101).

Regarding claim 13, Beecher/Dreyfus teach the device formed by the above claims (“Surface formation obtainable with a process according to claim 1”) (Figure 1).

Regarding claim 14, Beecher/Dreyfus teach device has a polytrifluoroethylene film (“first layer with an ultraphobic surface”) and substrate layers (“carrier layer” “several layers”) (Figure 1: 101 and 102) applied by screen printing, electrospray, and making the area prior to deposition (“applied reversibly on a carrier layer”). The maximum local flatness deviation of the surface formation on a length of 100 mm would intrinsically be <100 µm.

Regarding claim 17, Beecher/Dreyfus teach the film can be epoxy resin (“characterised in that the first layer is glued to the carrier layer”) (Pg. 9 lines 1-5).



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Regarding claim 18, Beecher/Dreyfus teach the film and substrate can be electrically conducting (“characterised in that there is an electrical contact between the first layer and the carrier layer”) (Pg. 6 line 17 and claim 5 line 1).

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecher et al (WO 00/67293) in view of Dreyfus (USP 5,854,486) and further in view of Nelson et al (USP 5,955,729).

Regarding claim 8, Beecher/Dreyfus teach the use of MALDI matrix such as cinnaminic acid derivatives, sinapinic acid and dihydroxybenzoic acid. Beecher/Dreyfus are silent about different MALDI matrix substances are applied to a sample carrier.

Nelson et al teach a method of identifying captured analytes using laser desorption/ionization in which same or different suitable MALDI matrix or matrices may be applied to the surfaces (col. 9 line 57-col. 10 line 23). It is desirable to use suitable MALDI matrix materials for analytes that differ in size.

Therefore it would have been obvious to one of ordinary skill in the art to apply different MALDI matrix substances to the sample carrier for the above advantages.

Regarding claim 9, Beecher/Dreyfus/Nelson teach the matrix in the openings (“that at least several MALDI matrix points or partial points each consisting of one MALDI matrix substance are built up”).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dmw

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

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